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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, AND WASHINGTON; THE COMMONWEALTHS OF MASSACHUSETTS AND VIRGINIA; and THE DISTRICT OF COLUMBIA,

ex rel. ZACHARY SILBERSHER,

Plaintiffs,

vs.

JANSSEN BIOTECH, INC., JANSSEN ONCOLOGY, INC., JANSSEN RESEARCH & DEVELOPMENT, LLC, JOHNSON & JOHNSON, and BTG INTERNATIONAL

Defendants.

Civil Action No. 19-12107 (KM) (JBC)

MEMORANDUM IN SUPPORT OF DEFENDANTS' JOINT MOTION TO DISMISS SECOND AMENDED COMPLAINT

Motion Date: Nov. 4, 2019

Document electronically filed

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INTRODUCTION

Zachary Silbersher is a patent attorney whose practice includes challenging patents through *inter partes* review ("IPR") proceedings and, in his words, "investigating invalid pharmaceutical patents that brand manufacturers use to protect their drugs from price competition." Second Amended Complaint ("SAC"), ECF 63 ¶ 16.[1] Recently, Mr. Silbersher has moved from counsel to litigant, converting patent claims into False Claims Act ("FCA") suits as an FCA Relator. To date, Relator has filed at least three nearly identical FCA actions premised on alleged inequitable conduct—a breach of the duty of candor owed to the U.S. Patent and Trademark Office ("USPTO").[2] In none of these cases is he the typical *qui tam* plaintiff—an employee, contractor, or other "insider" exposing misconduct. Quite the contrary, Relator has no relationship with Defendants. Instead, as the SAC makes clear, Relator has simply repackaged publicly available information and arguments made previously in various patent-related proceedings and now presents them as purported fraud. As such, Relator's allegations are precluded by the FCA's public disclosure bar. Moreover, even after further amending his Complaint in the wake of the J&J Defendants' prior motion to dismiss, Relator has still failed to plead sufficiently all the elements of an FCA action.

The SAC should be dismissed as to newly added Defendant BTG International ("BTG") for two additional reasons. First, as the SAC acknowledges, BTG had no role in the prosecution of the patents at issue and thus could not have caused the presentation of false claims or done so

[1] *See* Kroub, Silbersher & Kolmykov PLLC, *Zachary Silbersher*, http://www.kskiplaw.com/silbersher.html (last visited Sept. 10, 2019).

[2] *See U.S. ex rel. Silbersher v. Valeant Pharm. Int'l, Inc.*, No. 18-cv-01496-JD (N.D. Cal. Oct. 23, 2018); *U.S. ex rel. Silbersher v. Allergan PLC*, No. 18-cv-03018-JCS (N.D. Cal. April 12, 2019). Relator is also litigating identical claims packaged as antitrust suits. *See In re: Restasis*, No. 18-md-02819-NG-LB (E.D.N.Y).

knowingly. Second, the SAC fails to identify a single act by BTG contributing to the alleged fraud. It thus completely fails to satisfy Federal Rule of Civil Procedure 9(b)'s demand for pleading specific facts supporting each element of the alleged fraud.

For all the reasons set forth herein, the SAC should be dismissed with prejudice.

BACKGROUND

Defendants are healthcare companies that developed and licensed (BTG) or market and sell (J&J) abiraterone acetate ("abiraterone"), which is marketed and sold under the brand name Zytiga.[3] SAC ¶ 5.[4] Zytiga is a prescription drug used with prednisone, a glucocorticoid, to extend the lives of patients with metastatic castration-resistant prostate cancer ("mCRPC")—an advanced and deadly form of prostate cancer resistant to traditional first-line treatments. *See id.* ¶¶ 5, 59. Zytiga was first approved for use with prednisone in 2011 by the U.S. Food & Drug Administration ("FDA") for use in chemo-refractory patients (*i.e.*, patients who had already undergone chemotherapy). Just a year later, in 2012, FDA expanded Zytiga's approval to include chemo-naïve patients (*i.e.*, patients who had not undergone prior chemotherapy) under the FDA's priority review program, which provides for an expedited six-month review of drugs that may offer major advances in treatment or provide a treatment when no adequate therapy exists. *See, e.g.*, Request for Judicial Notice ("RJN"), Ex. C at 45 of 384 (PDF page).

Relator alleges that Defendants violated the FCA by submitting or causing to be submitted

[3] "Defendants" are Janssen Biotech, Inc., Janssen Oncology, Inc., Janssen Research & Development, LLC, Johnson & Johnson ("J&J Defendants") and BTG International Limited ("BTG").

[4] While Defendants accept Relator's well-pled allegations for this motion, if this matter proceeds, Defendants will vigorously dispute Relator's false, misleading, and legally insufficient claims. Additionally, Defendants have filed a Request for Judicial Notice that includes publicly disclosed articles containing information Relator relies on in the SAC. Defendants cite these articles to show that Relator's case is built entirely on public information. The inclusion of these articles does not indicate that Defendants necessarily accept or concede any statements made in the articles.

false claims for payment for Zytiga to various federal and state programs since December 2016. SAC ¶¶ 107–119. Relator does not claim that Defendants factually misrepresented the product sold, the quantity in which it was sold, or the contractual price for reimbursement. Rather, Relator contends that Defendants—through an attenuated series of events—corrupted the entire market for Zytiga, such that charging the price to which the federal Government voluntarily agreed through a long-established pricing formula was itself fraudulent.

Before a drug product may be reimbursed through various federal programs, a vendor must first enter into a Master Agreement ("MA") and a Pharmaceutical Price Agreement ("PPA") with the federal Government. *Id.* ¶ 112. A PPA provides the Government with the Average Manufacturer Price ("AMP") paid by commercial customers. *Id.* Federal law sets a Federal Ceiling Price ("FCP") that limits the price paid by the Government for any pharmaceutical to no more than 76% of the AMP. *Id.*

In order to qualify for reimbursements, a product must also appear on the Federal Supply Schedule ("FSS"), *id.*, which lists negotiated prices the federal Government pays for various products. To list a product on the FSS, an applicant must provide pricing information for both their "Most Favored Customer"—*i.e.*, the customer that pays the lowest price—and a "Tracking Customer"—*i.e.*, a customer whose price is tracked to "ensur[e] that prices remain fair and reasonable.'" *Id.*; *see also id.* ¶¶ 113–116. In negotiating prices, the General Services Administration ("GSA") issues a document (the "Solicitation") that explains the structured review procedures for contracting officers to determine whether the prices offered are "fair and reasonable." *Id.* ¶ 114.[5] The FSS Solicitation requires applicants to submit accurate pricing data,

[5] The GSA has delegated its authority to the Department of Veterans Affairs ("VA") for pharmaceutical products listed on the FSS. 48 C.F.R. § 8.402(a).

including the AMP and most-favored-customer information, and its terms give the Government the option to cancel a contract if inaccurate information is provided. *Id.*

Relator does not allege that Defendants submitted incorrect pricing data. Nor does Relator suggest that Defendants misapplied the statutory pricing formula. Rather, Relator alleges that the market price for Zytiga itself had been unlawfully inflated and was therefore *per se* not "fair and reasonable" or otherwise appropriate. *Id.* ¶ 117. Specifically, Relator alleges Defendants rigged the market price for Zytiga by unlawfully excluding generic competitors from marketing mCRPC treatments using abiraterone and prednisone through sham infringement litigation under the Hatch-Waxman Act. *Id.* ¶ 105.

Historically, use of Zytiga has been covered by two patents: U.S. Patent No. 5,604,213 ("the '213 Patent"), *see* RJN, Ex. A, which expired in December 2016, and U.S. Patent No. 8,822,438 ("the '438 Patent"), *see* RJN, Ex. B, granted in 2014. *See* SAC ¶¶ 92–93. Following issuance by the USPTO, Defendants listed the '438 Patent in the Orange Book. *Id.* ¶ 92. Several generic manufacturers subsequently filed abbreviated new drug applications ("ANDAs") containing Paragraph IV certifications contesting the '438 Patent's validity. *Id.* ¶ 94. In response, on July 31, 2015, Defendants filed suit for infringement in this District, triggering the Hatch-Waxman Act's temporary stay on all FDA approvals of generic abiraterone. 21 U.S.C. § 355(c)(3)(C); *see also* SAC ¶¶ 51, 99.[6]

The infringement suit, Relator argues, was a "sham." SAC ¶ 105. In Relator's estimation,

[6] Any manufacturer submitting an ANDA, *i.e.*, an application to market a generic product, may indicate whether the proposed drug implicates a patent listed in the Orange Book, and, if so, must certify that the patent is either not infringed or is invalid (a "Paragraph IV certification"). *See* 21 C.F.R. § 314.94(a)(12)(i)(A)(4); SAC ¶ 48(d). If a patent-holder files an action for infringement within 45 days of receiving notice of the certification, the Hatch-Waxman Act automatically stays the FDA from approving the relevant ANDAs—thereby stalling generic entry into the market—for 30 months or until a district court enters a judgment of non-infringement or invalidity. 21 U.S.C. § 355(c)(3)(C).

the purpose of the lawsuit was not to enforce the '438 Patent, but to exclude generic competition from the market. *Id.* That is, the lawsuit was "objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits"—akin to Rule 11 frivolousness, *Prof'l Real Estate Inv'rs, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60, 65 (1993)—even though Hatch-Waxman infringement actions are presumptively reasonable, *In re Wellbutrin XL Antitrust Litig.*, 868 F.3d 132, 149 (3d Cir. 2017). Relator contends that the statutorily mandated stay had the allegedly desired effect, allowing Defendants to continue to charge artificially inflated prices for Zytiga. SAC ¶¶ 99, 108.

But none of these events, together or in isolation, offers any basis to suggest that Zytiga's price was not "fair and reasonable." Instead, Relator's claims depend on purported fraud in a different proceeding years earlier before a different Government agency—the USPTO.

When the FDA first approved Zytiga in 2011, its use was covered only by the '213 Patent, issued in 1997 and claiming the compound abiraterone acetate. *See* RJN, Ex. A. In 2011, J&J filed application number 13/034,340 ("the '340 Application") for a method of administering therapeutically effective amounts of abiraterone acetate in combination with therapeutically effective amounts of prednisone to treat prostate cancer.[7] SAC ¶ 68. The USPTO initially denied the '340 Application for obviousness, before concluding that secondary considerations—such as the claimed invention's commercial success—supported non-obviousness. *Id.* ¶¶ 75–76. In 2014, it issued the '438 Patent. *Id.* ¶¶ 25, 85. Relator alleges that in presenting Zytiga's history of commercial success to the USPTO, Defendants made "false and misleading representations," thereby fraudulently inducing the USPTO to issue the '438 Patent. *See id.* ¶ 90.

[7] The '340 Application was a continuation of patent application number 11/844,440 ("the '440 Application"), filed by Cougar Biotechnology ("Cougar") in 2007, which was subsequently abandoned. *See* RJN, Ex. B. J&J acquired Cougar in May 2009.

Thus, the submission of claims for payment to the Government is far removed in time and space from any purportedly false statements. Under Relator's theory: Defendants defrauded the USPTO into issuing a patent; which Defendants listed in the Orange Book; which caused generic manufacturers to file Paragraph IV certifications; which allowed Defendants to file an infringement action; which triggered a stay of approval; which temporarily prevented generics from entering the market; which allowed Defendants to charge higher prices for Zytiga; which elevated the market prices submitted to the VA; which misled Government officials into agreeing to a price for Zytiga that was too high; which made Zytiga's federal list price not "fair and reasonable"; which made claims for reimbursement at that price false. As explained below, this theory fails for multiple reasons.

Relator was not the first (nor the second, nor even the third) party to challenge the '438 Patent and dispute the commercial success of the claimed invention. In Defendants' infringement action, filed before this Court in July 2015, the defendant generic companies contested the validity of the '438 Patent. After that suit was filed, beginning on December 4, 2015, five IPR[8] petitions were filed by generic pharmaceutical companies, contending similarly that the claimed invention was obvious and that Zytiga's commercial success was not attributable to that claimed invention. IPR proceedings are public, yet not until December 2017—more than two years later and following completion of dispositive briefing and oral argument in each of the IPRs—did Relator file this action under seal.

Relator's Complaint borrows liberally from the IPRs, contending that the '438 Patent should never have issued. *Id.* ¶¶ 63–91. Relator alleges, just as the IPR challengers did, that

[8] An IPR is a statutory procedure by which a third party may request cancellation of a patent claim because it does not meet the standards for patentability. *See* 35 U.S.C. §§ 311–319.

Defendants misrepresented specific market-share data relating to Zytiga by withholding competitor FDA approval dates and using improper metrics of commercial success, and, in so doing, overstated Zytiga's commercial success. *Id.* ¶¶ 82–86; *see infra* at 13–17. Relator then lists an assortment of additional alleged misstatements or omissions—some of which again parallel charges made in the IPRs. SAC ¶ 87(a)–(i); *see infra* at 13–17. He contends that Defendants acted in bad faith and that the USPTO awarded the '438 Patent solely because of these misstatements and omissions. SAC ¶¶ 82, 85–86.

In January 2018, within a month of Relator's filing this action, and after weighing the record developed through contentious evidentiary proceedings, the Patent Trial & Appeal Board ("PTAB") issued final decisions deeming the '438 Patent claims unpatentable. On September 17, 2018, following its investigation into Relator's claims, the United States declined to intervene in this action, with the Plaintiff States similarly declining on October 25, 2018. On October 31, 2018, following years of contested litigation culminating in a nine-day bench trial, this Court issued a decision finding the '438 Patent invalid. *See BTG Int'l Ltd. v. Amneal Pharm. LLC*, 352 F. Supp. 3d 352 (D.N.J. 2018). After reviewing the considerable evidence presented by both sides, the Court recognized that "this abiraterone product has enjoyed commercial success." *Id.* at 387. And, when reviewing the secondary considerations relevant to determining a patent's validity, the Court also found that "there is evidence supporting the unmet-need or failure-of-other factors," even if it was not "powerful" evidence." *Id.* at 388–89.[9]

Throughout the various challenges to the '438 Patent, even after the federal and state

[9] The Federal Circuit consolidated the appeals from the PTAB and this Court, affirmed the PTAB's order determining that the '438 Patent claims were unpatentable, and dismissed the appeal from this Court's order as moot. *See BTG Int'l Ltd. v. Amneal Pharm. LLC*, 923 F.3d 1063 (Fed. Cir. 2019). Neither this Court nor the Federal Circuit suggested that Defendants obtained the '438 Patent through inequitable conduct or any other similar fraudulent acts.

Governments declined to intervene, and to this day, the federal Government and the state Governments have continued to pay for Zytiga. *See, e.g.*, SAC ¶ 144 (alleging that the federal Government "paid and continues to pay the claims that the Government would not have paid but for Defendants' illegal conduct").

The seal was lifted on October 20, 2018, and the J&J Defendants were served. At that time, the case was pending in the Northern District of California. The J&J Defendants moved to transfer the case to this Court and subsequently moved to dismiss for failure to state a claim. ECF 30; ECF 32. The Honorable Jon S. Tigar of the Northern District of California ordered the case transferred and did not rule on the pending motion to dismiss. ECF 51.

While the then-pending motion to dismiss identified various irremediable defects in Relator's Amended Complaint, the J&J Defendants consented to allow Relator to amend. ECF 61. Relator filed the SAC, adding BTG as a defendant, and this joint motion follows.

LEGAL STANDARDS

A complaint must be dismissed if it does not "state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "[L]abels and conclusions" or "formulaic recitation[s] of the elements of a cause of action" are insufficient, as are "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 555). Because FCA claims are premised on fraud, they must be pled with the particularity demanded by Rule 9(b). *See, e.g.*, *Foglia v. Renal Ventures Mgmt., LLC*, 754 F.3d 153, 156–57 (3d Cir. 2014). In reviewing the sufficiency of the complaint, courts may consider the contents of the complaint and its attached exhibits, documents incorporated into the complaint by reference, and matters subject to judicial notice. *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322–23 (2007). In its analysis,

the Court must accept the complaint's well-pleaded facts as true but may disregard legal conclusions, including ones couched as factual allegations. *See In re Plavix Mktg., Sales Practices & Prod. Liab. Litig.*, 123 F. Supp. 3d 584, 593 (D.N.J. 2015) (*Plavix I*). Dismissal with prejudice is appropriate where, as here, a third amended complaint would demonstrate undue delay or be futile, particularly when Relator "was put on notice as to the deficiencies in his complaint, but chose not to resolve them." *U.S. ex rel. Schumann v. Astrazeneca Pharm. L.P.*, 769 F.3d 837, 849 (3d Cir. 2014).

ARGUMENT

I. RELATOR'S CLAIMS ARE PRECLUDED BY THE PUBLIC DISCLOSURE BAR

The FCA prohibits relators from asserting claims premised on facts that are "substantially the same" as previously publicly disclosed facts, unless the relator can demonstrate that he is an "original source" of the information. 31 U.S.C. § 3730(e)(4); *see U.S. ex rel. Moore & Co., P.A. v. Majestic Blue Fisheries, LLC*, 812 F.3d 294, 297 (3d Cir. 2016). "A disclosure is 'sufficiently public' if the information therein 'would have been equally available to strangers to the fraud transaction had they chosen to look for it as it was to the relator.'" *Plavix I*, 123 F. Supp. 3d at 596. In this way, the public disclosure bar "strike[s] a balance between encouraging private persons to root out fraud and stifling parasitic lawsuits." *Graham Cty. Soil & Water Conservation Dist. v. U.S. ex rel. Wilson*, 559 U.S. 280, 295 (2010). Relator's claims fall squarely on the parasitic side as they are based on publicly disclosed information for which he is not an original source. The Court should therefore dismiss the SAC on this basis alone.

A. Relator's Essential Allegations Were Previously Disclosed

Relator's lawsuit is the paradigmatic "parasitic lawsuit[]" Congress sought to preclude. *U.S. ex rel. Zizic v. Q2Administrators, LLC*, 728 F.3d at 235. Drawn from patent filings, court pleadings, IPR petitions, and media searches, the SAC's allegations rely entirely on publicly available information, repackaged for Relator's pecuniary gain.

The FCA directs courts to dismiss *qui tam* suits when "substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed" "(i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party; (ii) in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or (iii) from the news media." 31 U.S.C. § 3730(e)(4)(A). As used in the statute, "allegation" refers to a "specific allegation of wrongdoing," whereas a "transaction" "raises an inference of fraud consist[ing] of both the allegedly misrepresented facts and the allegedly true state of affairs." *United States v. Omnicare, Inc.*, 903 F.3d 78, 83 (3d Cir. 2018), *petition for cert. filed sub nom. Pharmerica Corp. v. U.S. ex rel. Silver* (U.S. Feb. 8, 2019) (No. 18-1044).

At bottom, the SAC rests on the notion that Defendants tricked the USPTO into agreeing that the invention claimed by the '340 Application (*i.e.*, the co-administration of therapeutically effective amounts of abiraterone with therapeutically effective amounts of prednisone) had enjoyed commercial success by (1) misrepresenting Zytiga's share of the market, as a measure of commercial success and/or (2) omitting information suggesting Zytiga's commercial success was not attributable to the claimed invention. *See* SAC ¶¶ 82–90.[10] But these core allegations were

[10] Although Relator ultimately claims (albeit without specificity) that Defendants made false claims to the Government payer that the price of Zytiga was fair and reasonable, SAC ¶¶ 113–118, the daisy-chain nature of the SAC requires Relator to show that Defendants' statements to the USPTO had not been previously publicly disclosed. In any event, Zytiga's FSS information is publicly available through the VA's website, thereby publicly disclosing that the Government accepted Defendants' offered price as "fair and reasonable." *See* RJN, Exs. GG, HH.

all previously disclosed through IPR petitions that similarly contended that the J&J Defendants mischaracterized the scale and source of Zytiga's commercial success.

Disclosure during an IPR proceeding qualifies as a public disclosure under the FCA both because an IPR proceeding is an administrative hearing to which the Government is a party and because it is a federal hearing or investigation. *See A-1 Ambulance Serv., Inc. v. California*, 202 F.3d 1238, 1244 (9th Cir. 2000) ("'Hearing' in this context is synonymous with 'proceeding,' and, for purposes of raising the public disclosure bar, encompasses publicly-filed documents, 'even if they are not the subject of a hearing.'" (citations omitted)). As the Federal Circuit recently recognized, an IPR "is similar to an agency enforcement action instituted by the USPTO 'upon information supplied by a private party' rather than civil litigation." *Regents of the Univ. of Minn. v. LSI Corp.*, 926 F.3d 1327, 1339 (Fed. Cir. 2019).[11] In an IPR, the USPTO "is acting as the United States in its role as a superior sovereign to reconsider a prior administrative grant." *Saint Regis Mohawk Tribe v. Mylan Pharm. Inc.*, 896 F.3d 1322, 1329 (Fed. Cir. 2018), *cert. denied*, 139 S. Ct. 1547 (2019).[12] For instance, the Director of the USPTO has sole discretion to institute an IPR based on a reasonable likelihood of success and the PTAB may continue to pursue an IPR to decision even if the petitioner stops participating. *Minnesota*, 926 F.3d at 1336; 35 U.S.C. §§ 314(a), 317(a). And, unlike a judicial body, the USPTO may intervene in any appeal from the PTAB's decision to defend that decision. *Minnesota*, 926 F.3d at 1337; 35 U.S.C. § 143. The Government's "central role," *Saint Regis Mohawk Tribe*, 896 F.3d at 1327, brings IPR proceedings

[11] *See* Brief for Federal Resp. at 25, *Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC*, 138 S. Ct. 1365 (2017) (No. 16-712) ("[A]lthough private challengers may assist the Board by identifying questionable patents and bringing forward new information and arguments, the Board's role is to protect the public interest in the integrity of existing patents, not to determine the respective rights of the patentee and challenger vis-à-vis each other.").

[12] *See Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2139–40 (2016) (an "important congressional objective" in enacting IPR was "giving the Patent Office significant power to revisit and revise earlier patent grants"); *Minnesota*, 926 F.3d at 1339.

well within the public disclosure bar. Notably, materials associated with an IPR proceeding, including petitions, briefs, hearing transcripts, and decisions by the PTAB, are compiled and posted publicly on the PTAB's website, where it reports out on America Invents Act patent challenges. *See Schindler Elevator Corp. v. U.S. ex rel. Kirk*, 563 U.S. 401, 407–08 (2011) (adopting the ordinary meaning of "report," for purposes of the public disclosure bar, as "something that gives information" or a "notification" or "[a]n official or formal statement of facts or proceedings" (quoting *Black's Law Dictionary* 1300 (6th ed. 1990))); *see also U.S. ex rel. Osheroff v. Humana Inc.*, 776 F.3d 805, 813 (11th Cir. 2015) ("District courts in the Eleventh Circuit and in other circuits have determined that the term [news media] includes publicly available websites.").

Moreover, the facts Relator claims Defendants *should* have disclosed to the USPTO were, in fact, so disclosed. For instance, many of the alleged "facts" or purported omissions were submitted to the Government as part of the federal hearing into J&J's patent application. *See A-1 Ambulance Serv.*, 202 F.3d at 1244; *Two-Way Media LLC v. Am. Online, Inc.*, 508 F. Supp. 2d 526, 530 (S.D. Tex. 2007) (referring to patent prosecution proceedings as "hearings"). The June 4, 2013 submission (the "June 4 submission") on which Relator places particular emphasis is also publicly available through the Public PAIR ("Patent Application Information Retrieval") database maintained on the USPTO's website that compiles prosecution histories and reports of patents and patent applications.[13] *See Schindler Elevator Corp.*, 563 U.S. at 407–08; *Fleetwood Grp., Inc. v.*

[13] Once published, patent applications are made publicly available through Public PAIR. *See* U.S. Patent & Trademark Office, *Published Patent Application Access and Status Information Sheet for Members of the Public*, https://www.uspto.gov/patents-application-process/patent-search/published-patent-application-access-and-status-information (last modified June 7, 2017) (directing members of the public to USPTO website for patent application publications). The '340 Application was published as of June 16, 2011. *See* RJN, Ex. OO, Notice of Publication. Subject to certain exceptions not applicable here, all documents submitted in connection with the '340 Application were thereafter viewable on Public PAIR.

Albert Hall Meetings, Ltd., No. 6:06-cv-859-Orl-19JGG, 2007 WL 9723102, at *2 n.2 (M.D. Fla. June 20, 2007) ("The Patent Office publishes an official record of its proceedings on the internet through the Patent Application Information Retrieval system ("PAIR"). PAIR displays information regarding patent application status and provides information for all actions taken by the Patent Office for a given application."). Yet others were publicly available through a host of online media sources. Thus, both Relator's allegations and the transactions that form the basis for his claims were publicly disclosed through channels recognized by the FCA: administrative hearings in which the federal Government was a party; federal hearings or investigations; federal reports; and the news media. *See Plavix I*, 123 F. Supp. 3d at 596 (online publications are "news media"); *see also Moore*, 812 F.3d at 302–03 ("news media" "likely describes a multitude of sources that would seldom come to the attention of the Attorney General").

1. Relator's Allegations Mirror Those Contained In Publicly Disclosed IPR Petitions

The five IPR petitions challenging the '438 Patent were lodged well before Relator filed the instant action and were all publicly available on the PTAB website at or near the time of filing between December 2015 and February 2017. The IPR petitions—filed by Amerigen Pharm., Ltd. (Dec. 5, 2015), Argentum Pharm. LLC (June 29, 2016), Mylan Pharm. Inc. (June 30, 2016), Wockhardt Bio AG (Aug. 10, 2016), and Actavis Laboratories FL, Inc., Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals of New York, LLC, Dr. Reddy's Laboratories, Inc., Dr. Reddy's Laboratories, Ltd., Sun Pharmaceuticals Industries, Ltd., Sun Pharmaceuticals Industries, Inc., Teva Pharmaceuticals USA, Inc., West-Ward Pharmaceutical Corp., and Hikma Pharmaceuticals, LLC (Feb. 8, 2017)—long predate Relator's FCA filing in December 2017. *See* Amerigen Pet., RJN, Ex. D; Mylan Pet., RJN, Ex. E; Wockhardt Pet., RJN, Ex. F. The Argentum petition was joined with the Amerigen IPR, and the Actavis, *et al*. petition was joined with the Mylan IPR. Once posted on the PTAB's on-line reporting site, the information was "equally available to

strangers to the fraud transaction had they chosen to look for it as it was to the relator." *Plavix I*, 123 F. Supp. 3d at 596. This alone should end the public disclosure inquiry.

But there is more. At least two of those petitions (Amerigen and Wockhardt), including their docket numbers, were reported in news articles pre-dating the filing of Relator's sealed complaint.[14] *See U.S. ex rel. Proctor v. Safeway, Inc.*, No. 11-cv-3406, 2016 WL 7017231, at *12 (C.D. Ill. Dec. 1, 2016) (article identifying lawsuit constitutes public disclosure). And three (Amerigen, Wockhardt, and Mylan) were disclosed in J&J's SEC filings, all submitted and publicly available on the SEC's EDGAR database in 2016—also well before the filing of Relator's first complaint.[15] *See U.S. ex rel. Ryan v. Endo Pharm., Inc.*, 27 F. Supp. 3d 615, 628 n.16 (E.D. Pa. 2014) (10-K filing constitutes public disclosure as a federal report).

The IPR petitions disclosed the bases of Relator's essential allegations. *First*, the IPRs asserted that Defendants failed to demonstrate a nexus between Zytiga's commercial success and the claimed invention. *Compare* Amerigen Pet., RJN, Ex. D at 48–52 (arguing that J&J "presented *no* evidence to suggest that the claimed invention, rather than the prior art abiraterone acetate, was responsible for any commercial success of Zytiga.®"); Mylan Pet., RJN, Ex. E at 51–54 (arguing that "any commercial success of Zytiga® has not been shown to derive from the claimed invention, *i.e.*, the combination of abiraterone acetate and prednisone"); Wockhardt Pet., RJN, Ex. F at 60–62 (arguing that Defendants "failed to provide any evidence [of a] nexus between the Zytiga® sales and the '438 patent"), *with* SAC ¶ 87(b)–(g), (i) (alleging facts, not disclosed to the USPTO, that purportedly demonstrate Zytiga's commercial success was attributable to other factors and

[14] *See* RJN, Ex. P at 1 (discussing the Amerigen petition) (June 6, 2016); RJN, Ex. Q at 1–2 (discussing the Wockhardt petition) (Feb. 7, 2017).

[15] *See* RJN, Ex. K (Nov. 4, 2016 10-Q); RJN, Ex. L (Aug. 4, 2016 10-Q); RJN, Ex. M (May 9, 2016 10-Q); RJN, Ex. N (Feb. 24, 2016 10-K).

lacked nexus to the claimed invention).

Relator merely repurposes those petitions' arguments that Zytiga's commercial success is owed to the "effectiveness of abiraterone acetate in treating prostate cancer," Amerigen Pet., RJN, Ex. D at 51; *see also* Mylan Pet., RJN, Ex. E at 53 (same); Wockhardt Pet., RJN, Ex. F at 60–62 (arguing commercial success cannot be based on characteristics of claimed method already known in the prior art), when he alleges: (i) the drug resistant nature of mCRPC limits the long-term efficacy of any one drug, therefore any new anti-cancer drug is likely to have some commercial success, SAC ¶ 87(b); (ii) "Zytiga was recommended in some cases because it was the least toxic" of available drugs, not because of any feature of the claimed invention, *id.* ¶ 87(d); and (iii) the alleviation of certain side effects, which Relator alleges was the innovation claimed by the '438 Patent, "may not have actually been a factor in the decision to prescribe or take Zytiga," *id.* ¶ 87(f).

Second, Relator's contentions that Defendants mischaracterized the market for mCRPC therapies and the commercial success of Zytiga's competitors, *id.* ¶ 84, are also lifted straight from the IPR petitions. For instance, Wockhardt attacked as misleading J&J's statement that Zytiga maintained its commercial success even after the introduction of competitor Xtandi, because Xtandi subsequently overtook Zytiga's market share. Relator cites that same Zytiga-to-Xtandi market shift. *Compare* Wockhardt Pet., RJN, Ex. F at 62–63 (loss of market share against Xtandi "is particularly notable in light of the applicants' argument during prosecution that Zytiga®'s continued commercial success after the introduction of Xtandi® was further evidence of the commercial success of the invention"), *with* SAC ¶ 84(a) (alleging that Xtandi overtook Zytiga in market share in the relevant market). Moreover, that Xtandi proceeded to exceed Zytiga in sales was also reported in the media. *See, e.g.*, RJN, Ex. R at 2 (business article).

Third, Relator rehashes the IPR petitions' efforts to undermine Defendants' definition of

the relevant market for measuring commercial success, going so far as to cite the same business presentation slide that J&J had submitted to the USPTO. Relator attacks the slide's market-share comparison as fraudulent because it compared Zytiga and Xtandi sales in a submarket for which Xtandi had not yet received FDA approval. *See* SAC ¶ 84(d); RJN, Ex. C at 58 of 384 (PDF page) (June 4, 2013 submission). The IPR petitions similarly challenged the data as "deficient" and contended that Zytiga's commercial success was, in fact, less robust. *See* Amerigen Pet., RJN, Ex. D at 49–50; Mylan Pet., RJN, Ex. E at 52–53.

Finally, Relator repeats the IPR petitions' arguments that the '213 Patent "blocked" the commercial development of abiraterone, thus "cast[ing] substantial doubt" on Zytiga's sales success. *Compare* SAC ¶ 87(e), *with* Amerigen Pet., RJN, Ex. D at 57–59 ("The ability of the patentees of the '213 to block additional research and development of abiraterone acetate limits the relevance of commercial success for the '438 patent."); Mylan Pet., RJN, Ex. E at 59–61 ("'213 patent was a blocking patent that limited economic incentives to develop the invention of the '438 patent."); Wockhardt Pet., RJN, Ex. F at 56–59 (discussing Janssen's "blocking exclusivity" of the '213 Patent). Critically, Relator goes a step further to repeat the canard that this "blocking patent" was not disclosed to the USPTO. *Compare* SAC ¶ 87(e), *with* Amerigen Pet., RJN, Ex. D at 34; Mylan Pet., RJN, Ex. E at 35. The allegation is not only derivative, it is false. The '213 Patent was disclosed publicly and to the USPTO through the '340 Application's specification. *See* RJN, Ex. I at 7, 10 ('340 Application specification). Additionally, medical journals reported that the exclusivity enjoyed by Zytiga due to the existing '213 composition patent would be extended upon that patent's expiration as a result of the newly granted method-of-use patent (*i.e.*, the '438 Patent).[16]

[16] *See, e.g.*, RJN, Ex. S at S492–93 (discussing how the '438 Patent will "extend the period of

As these comparisons demonstrate, Relator's fraud allegations are "substantially similar" to contentions made in the IPR petitions. *Moore*, 812 F.3d at 301. The Court could stop here.

2. The Transactions Underlying Relator's Allegations Were Publicly Disclosed

The public disclosure bar requires dismissal not only because Relator's *allegations* were publicly disclosed but also because the *transactions* that form their basis were publicly disclosed, either in the patent prosecution itself or through widely available internet reporting. *See* 31 U.S.C. § 3730(e)(4) (public disclosure bar triggered by disclosure of "allegations or transactions").

To discern whether a transaction giving rise to "an inference of fraud [] has been publicly disclosed such that the public disclosure bar is triggered," the Third Circuit applies "a formula of sorts … X + Y = Z," where "Z represents the allegation of fraud and X and Y represent its essential elements," *i.e.*, the misrepresented facts and the true state of affairs. *Omnicare*, 903 F.3d at 83–84. Here, all of the "X"—allegedly misleading statements or omissions in the June 4 submission—were provided to the USPTO during the patent prosecution. SAC ¶¶ 82–84, 87.

And the "Y"—the information Relator claims *should* have been disclosed to the USPTO—was included in that same June 4 submission to the Government or disclosed through other media sources. As it concerned Zytiga's market share, Relator alleges that Defendants misled the USPTO by: (1) comparing Zytiga's market share in the chemo-naïve submarket to that of Xtandi, when Xtandi had yet to be FDA-approved for that submarket, *id.* ¶ 84(a)–(d); (2) withholding the dates of Xtandi's FDA approvals, *id.* ¶ 84(d); and (3) submitting market share-data based on patient-share rather than direct sales, "because patients suffering from prostate cancer often take many drugs," *id.* ¶ 84(e). But this too was all publicly disclosed on PAIR through the June 4 submission. For instance, the June 4 submission included an FDA press release that announced Xtandi's FDA

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exclusivity" beyond the preexisting '213 Patent).

approval date for the *chemo-refractory* market specifically, and the purportedly misleading slide referenced in the SAC expressly distinguished the two submarkets (chemo-refractory and chemo-naïve) in which the products were being compared. J&J could hardly be expected to disclose Xtandi's approval date for the chemo-naïve market, as that approval had not yet occurred. *Id.* ¶ 84(a). Moreover, Xtandi's first FDA approval for chemo-refractory patients and the later, *September 2014*, approval for chemo-naïve patients—after the issuance of the '438 Patent—were reported in the press.[17] The press also reported on Xtandi's overtaking Zytiga in sales in 2015. *Id.*[18] The June 4 submission further made clear that the market share comparison was based on patient data (not direct sales), RJN, Ex. C at 58 of 384 (PDF page), and also that there was a critical need for second-line therapies for mCRPC patients (*i.e.*, mCRPC patients need and take multiple drugs), *id.* at 41–46 (FDA press releases discussing need for and approval of second-line or alternative drug therapies). This latter point has also been covered by scientific and medical articles and was discussed in the '340 Application specification submitted to the USPTO and available on PAIR.[19]

Relator also contends that Defendants should have disclosed that: (1) other non-oral cancer drugs "have been far more successful than Zytiga," SAC ¶ 87(a); (2) drug-resistant mCRPC patients must frequently switch medications, which "*suggests* that any new mCRPC drug is likely to have some immediate commercial success," *Id.* ¶ 87(b) (emphasis added); and (3) mCRPC

[17] *See, e.g.*, RJN, Ex. T at 1 (journal article) (announcing FDA approval for chemo-naïve market); RJN, Ex. U at 1 (journal article) (announcing FDA approval for chemo-refractory market).

[18] *See, e.g.*, RJN, Ex. JJ at 2 (discussing Xtandi surpassing Zytiga in sales by 2015).

[19] *See, e.g.*, RJN, Ex. V at 170–71 (journal article) (mCRPC patients often need multiple lines of treatment "due to inherent or acquired resistance" of the disease); RJN, Ex. I at 1–2 (discussing need for multiple treatments and that hormone therapies can be used in addition to local therapies); RJN, Ex. KK at 2–3 (discussing the major challenge of resistance to abiraterone and enzalutamide typically developed after 11 to 18 months of treatment, noting those patients can switch to another androgen-receptor targeted drug).

drugs "extend a patient's life by a few months," which Relator infers to mean that the alleviation by prednisone of abiraterone's side effects "may not" factor in the decision to take Zytiga, *id.* ¶ 87(f). According to Relator, disclosing these "facts" would have shown that Zytiga's commercial success was attributable to abiraterone's anti-cancer properties and not the claimed invention.[20] Whatever their alleged import, the underlying facts were disclosed in the June 4 submission[21] and were also discussed in various scientific articles.[22] *See, e.g., U.S. ex rel. Repko v. Guthrie Clinic, P.C.*, No. 3:04CV1556, 2011 WL 3875987, at *7 (M.D. Pa. Sept. 1, 2011) ("'information in scholarly or scientific periodicals' qualifies as 'news media'" (quoting *U.S. ex rel. Alcohol Found., Inc. v. Kalmanovitz Charitable Found., Inc.*, 186 F. Supp. 2d 458, 463 (S.D.N.Y. 2002))).

Next, Relator alleges Defendants should have disclosed that Zytiga enjoyed certain competitive advantages contributing to overall commercial success that were unrelated to the claimed invention, including that: (1) Zytiga "does not sequence well" with Xtandi and therefore had a natural edge because Zytiga launched first, SAC ¶ 87(c); and (2) Zytiga has lower toxicity, was cheaper, and offers a more convenient method of administration than its competitors, *id.*

[20] Relator's allegations reveal his own misunderstanding of what was claimed by the '340 Application, which sought to patent the combination of a therapeutically effective amount of abiraterone and a therapeutically effective amount of prednisone for the treatment of cancer. RJN, Ex. B. In other words, the '340 Application claimed methods of using a combination therapy in which both abiraterone and prednisone contributed to the anti-cancer effects distinct from the use of abiraterone by itself (covered in the '213 Patent).

[21] J&J provided the USPTO with information concerning the drug-resistant nature of the disease and the value of second-line therapies. RJN, Ex. C at 41–46 of 384 (PDF page). The FDA press releases in the June 4 submission also provide the "median overall survival rate" for patients taking the mCRPC drugs. *Id.*

[22] The success of other non-oral cancer drugs has been discussed. *See, e.g.*, RJN, Ex. II at 1 (discussing the successful launch of intravenous cancer drug Avastin). The drug-resistant nature of prostate cancer is well documented. *See, e.g.*, RJN, Ex. W at 1–2 (scientific article) (discussing prostate cancer's "resistance to anti-androgen therapies"); RJN, Ex. X (scientific article) (same). Zytiga's effect in prolonging survival is also well disclosed in the media. *See, e.g.*, RJN, Ex. Y at 2 (N.Y. Times article).

¶ 87(d), (g)–(h). Again, these facts were all publicly disclosed. The sequencing relationship between Zytiga and Xtandi was the subject of scientific study and publicly discussed in medical publications.[23] The "relatively low toxicity profile" of abiraterone was disclosed in at least one scientific article (included as part of the '340 Application),[24] the American Urology Association's 2013 guidelines[25] (which appear to be cited in SAC ¶ 87(d)), and is readily inferred from the unremarkable observation that Zytiga is not a chemotherapy but a hormone-based therapy, which are known to be less toxic.[26] Additionally, the 2013 price points for Zytiga, Xtandi, and Jevtana were publicly available in the media,[27] and each drug's method of administration was available on the drug's information website.[28] Publicly sourced articles have also documented a preference for oral over intravenous therapies.[29]

[23] *See, e.g.*, RJN, Ex. Z (scientific article) (noting an abiraterone (Zytiga)-to-enzalutamide (Xtandi) sequence "might have more favorable efficacy" than an enzalutamide-to-abiraterone sequence); RJN, Ex. X at 1 (discussing cross-resistance of abiraterone and enzalutamide).

[24] RJN, Ex. O at 46. The '438 Patent also expressly lists this article as disclosed during its prosecution. *See* RJN, Ex. B at 2.

[25] RJN, Ex. G at 435 (American Urology Association 2013 Guidelines).

[26] *See* RJN, Ex. AA at 1 (scientific article) (noting doctors typically use hormone therapy as a first treatment "because hormone therapy is less toxic and has fewer side effects than chemotherapy").

[27] *See* RJN, Ex. BB at 3 (news article) ("Zytiga costs $5,500 a month, while Xtandi gets $7,450 a month."); RJN, Ex. CC at 2 (N.Y. Times article) (noting Jevtana "costs about $8,000 every three weeks").

[28] A review of the brand name drugs' webpages, as those sites existed approximately two months before Relator filed his first complaint in December 2017, confirms that the methods of administration for Zytiga and its competitors were fully disclosed. *See* RJN, Ex. DD at 2, 4 (Zytiga's website as of Oct. 15, 2017) (Zytiga is an "oral, once-daily" "prescription medication that is used along with prednisone"); RJN, Ex. EE at 1 (Xtandi's website as of Oct. 6, 2017) ("Swallow Xtandi capsules whole."); RJN, Ex. FF at 1 (Jevtana's website as of Oct. 5, 2017) ("Jevtana is an infusion medicine."). This information is also disclosed in scientific and news articles. *See* RJN, Ex. LL at 1 (scientific article) ("Zytiga tablets should be swallowed whole with water."); RJN, Ex. MM at 2 (scientific article) ("Xtandi, an androgen receptor inhibitor, is taken orally, once a day."); RJN Ex. NN at 2 (news article) ("Sanofi sells Cabazitaxel injection under brand name Jevtana.").

[29] *See, e.g.*, RJN, Ex. R at 3 ("Oral formulations can be favourable over injections and infusions that require healthcare facility visits.").

3. The Allegations And Transactions Described In Relator's Complaint Are "Substantially The Same" As The Publicly Disclosed Information

Whether taken separately or together, there can be no doubt that the allegations and transactions in the SAC are "substantially the same" as the publicly disclosed information. The SAC nowhere identifies non-public, privately held information in support of Relator's lawsuit and is virtually indistinguishable from publicly available information. *See U.S. ex rel. Yagman v. Mitchell*, 711 F. App'x 422, 423–24 (9th Cir. 2018) (allegations should be sufficiently specific to distinguish them from publicly available information). When the information is already publicly disclosed, "the mere application of experience or deductive skills to such information or the addition of another allegation to the already articulated accusation of fraud does not create a new, non-barred, claim of fraud." *Omnicare*, 903 F.3d at 89–90. Relator's labor in compiling these facts and molding them into his fraud narrative does not launder them of prior disclosure. *See id.* at 89; *see also A-1 Ambulance Serv.*, 202 F.3d at 1245. Rather, his claims are barred because they are "supported by" and "substantially similar to" the described public disclosures. *Omnicare*, 903 F.3d at 84.

B. Relator Is Not An Original Source

When a *qui tam* claim draws upon publicly disclosed allegations or transactions, the relator may avoid the public disclosure bar only by demonstrating that he is an "original source." That is, a relator must be someone who (1) "prior to a public disclosure … voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based" or (2) "has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing" the *qui tam* lawsuit. 31 U.S.C. § 3730(e)(4)(B). Relator Silbersher is neither.

As an initial matter, Relator has not pled any facts demonstrating that his voluntary

disclosures to the Government pre-dated the foregoing public disclosures. *Compare* SAC ¶¶ 16–17 (pleading voluntary disclosures were made in November 2, 2018 and June 5, 2019) *with* RJN, Exs. C–FF, II–NN (all disclosures were made prior to 2018). Indeed, according to Relator, his first voluntary disclosure to the Government occurred nearly a year *after* the filing of his first complaint in this action (December 2017).

Furthermore, Relator does not plead any facts to support his claim to be an original source beyond his own naked say-so. *See* SAC ¶¶ 16–17. The SAC pleads no independent knowledge that adds materially to the public disclosures on which his alleged allegations and transactions are based. *See In re Plavix Mktg. Sales Practices & Prod. Liab. Litig.*, 315 F. Supp. 3d 817, 824–25 (D.N.J. 2018), *appeal docketed*, No. 18-2472 (3d Cir. July 3, 2018) (*Plavix III*). Relator alleges that he independently provided the Government with "facts demonstrating that Defendants failed to disclose" that Xtandi was not yet approved for the chemo-naïve submarket and "facts demonstrating that Defendants withheld material information … that the claimed commercial success of Zytiga lacked any nexus to the claimed invention in the '438 Patent." SAC ¶ 17. But he does not allege what those facts were. And in any event, those "facts" are drawn from the publicly disclosed sources described above. Relator fails to contribute any information that is "distinct from what was publicly disclosed, that adds in a significant way to the essential factual background: the who, what, when, where, and how of the events at issue." *Moore*, 812 F.3d at 306. Rather, Relator gestures vaguely to unspecified "independent research and investigation" without ever identifying the nature of his research or investigation or how it supplemented what was previously disclosed. *See* SAC ¶ 16.[30] *See U.S. ex rel. Bartlett v. Tyrone Hosp., Inc.*, 234

[30] The SAC's lack of specifics is particularly telling given that when repleading Relator had the benefit of J&J's first motion to dismiss, including the numerous channels through which the claimed facts and allegations were previously disclosed.

F.R.D. 113, 118–19 (W.D. Pa. 2006) (court cannot assume facts not pled).

In sum, every aspect of Relator's claims was publicly disclosed before he filed suit. Far from being an original source of the information on which his claims rest, Relator has largely copied contentions raised by others in earlier patent challenges—contentions that have been posted on publicly available Government websites and covered in the news media. His parasitic claims should be dismissed.[31]

II. RELATOR FAILS TO PLEAD ESSENTIAL ELEMENTS OF HIS CLAIMS

An FCA complaint must plead "four elements: falsity, causation, knowledge, and materiality." *U.S. ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 487 (3d Cir. 2017) (citations omitted). Because the FCA sounds in fraud, each must be pleaded with particularity, supported by "'all of the essential factual background that would accompany the first paragraph of any newspaper story—that is, the who, what, when, where and how of the events at issue.'" *Moore* 812 F.3d at 307 (quoting *In re Rockefeller Ctr. Props., Inc. Securities Litig.*, 311 F.3d 198, 217 (3d Cir. 2002)). Relator fails to allege these elements adequately.

A. Relator Fails To Plead A False Claim Or A False Statement Connected To A Claim For Payment

A false claim is the *sine qua non* of FCA liability. *Bartlett*, 234 F.R.D. at 124. The SAC invokes two theories of falsity: a certification theory (both express and implied) and a similar, but narrow, promissory fraud or "fraud-in the-inducement" theory. Neither holds water.

1. Relator Fails To Plead A False Statement Connected To A Claim For Reimbursement

The FCA does not reach all false statements made to the Government; rather, to be

[31] *See U.S. ex rel. Freedom Unlimited, Inc. v. City of Pittsburgh*, 728 F. App'x 101, 103 (3d Cir. 2018) ("FCA includes this public disclosure bar because a relator should not be able to profit from a *qui tam* case that it predicates on information developed by other parties.").

actionable under the FCA, the false statement must be material to a claim for payment. *In re Plavix Mktg Sales Practice and Products Liab. Litig.*, 332 F. Supp. 3d 927, 951 (D.N.J. 2017) (*Plavix II*) (FCA is concerned with false claims and does not reach all fraud on the Government). As an initial matter, Relator fails to identify any false statement made to the Government payer in connection with a *claim* for reimbursement. Nowhere does Relator allege that Defendants submitted or caused to be submitted a claim for payment that was factually false or contained inaccurate information about Zytiga or its price. Rather, Relator contends without elaboration that Defendants "expressly and implicitly" certified—to an unidentified person at an unidentified time—that the price for Zytiga was "fair and reasonable" or "not tainted by fraud." SAC ¶ 110. But the SAC fails to allege that Defendants actually submitted or caused to be submitted to the Government payer a claim that "falsely certif[ied] that [defendants were] in compliance with a material statute, regulation, or contractual provision." *Plavix II*, 332 F. Supp. 3d at 939 (quoting *U.S. v. Eastwick Coll.*, 657 F. App'x 89, 93–94 (3d Cir. 2016)); *see also U.S. ex rel. Wilkins v. United Health Grp.*, 659 F.3d 295, 305 (3d Cir. 2011). At bottom, Relator nowhere describes the specific contents, nature, location, date, or form of any allegedly offending claim for reimbursement submitted to the Government payer, let alone any specified certification or representation concerning the price for Zytiga, much less any specified certification or representation that the price of Zytiga was "fair and reasonable" in accordance with any statutory or regulatory term as part of a claim for payment.[32]

Nor has Relator alleged a cognizable impliedly false claim. If "a defendant makes

[32] Nor can Relator rely on alleged misrepresentations to the USPTO in support of an express certification theory, because "the relevant inquiry when determining liability under" that theory "is whether warranties of statutory and regulatory compliance were made *to the Government payer*." *U.S. ex rel. Schimelpfenig v. Dr. Reddy's Labs. Ltd.*, No. 11-4607, 2017 WL 1133956, at *8 n.1 (E.D. Pa. Mar. 27, 2017) (emphasis added).

representations in submitting a claim but omits its violations of statutory, regulatory, or contractual requirements, those omissions can be a basis for liability if they render the defendant's representations misleading with respect to the goods or services provided." *Universal Health Servs., Inc. v. U.S. ex rel. Escobar*, 136 S. Ct. 1989, 1999 (2016). Such a claim requires two conditions: "first, [that] the claim does not merely request payment, but also makes specific representations about the goods or services provided; and second, the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths." *Id.* at 2001; *see also Eastwick Coll.*, 657 F. App'x at 94 (citing *Escobar*).

Post-*Escobar* decisions recognize the importance of "specific representations" to anchor an implied certification theory. *See U.S. ex rel. Rose v. Stephens Inst.*, 909 F.3d 1012, 1017–18 (9th Cir. 2018); *U.S. ex rel. Nargol v. DePuy Orthopaedics, Inc.*, 865 F.3d 29, 37 (1st Cir. 2017) (identifying a specific misrepresentation); *United States v. Sanford-Brown Ltd.*, 840 F.3d 445, 447 (7th Cir. 2016) (requiring evidence of representations in connection with claim for payment); *U.S. ex rel. Smith v. Wallace*, 723 F. App'x 254, 256 (5th Cir. 2018) (requiring evidence of specific representations that were misleading half-truths). Other courts in the Third Circuit have likewise applied *Escobar*'s two-pronged analysis. *See Plavix II*, 332 F. Supp. 3d at 939; *U.S. ex rel. Bahnsen v. Bos. Sci. Neuromodulation Corp.*, No. CV 11-1210, 2017 WL 6403864, at *7 (D.N.J. Dec. 15, 2017); *Pink v. Khan*, No. CV 13-4924, 2018 WL 5831222, at *5 n.11, *6 n.14 (E.D. Pa. Nov. 7, 2018); *United States v. Select Specialty Hosp.-Wilmington, Inc.*, No. 1:16-CV-347, 2018 WL 1568874, at *4 (D. Del. Mar. 30, 2018).[33]

[33] One decision in this District permitted a relator to proceed on an implied false certification theory in the absence of specific representations concerning a good or service, on the theory that "all claims for payment implicitly represent that the billing party is legally entitled to payment." *U.S. ex. rel. Simpson v. Bayer Corp.*, 376 F. Supp. 3d 392, 407 (D.N.J. 2019) (quoting *Escobar*,

Relator fails to meet his burden. The lack of factual specifics in the SAC concerning the claims themselves precludes any showing that Defendants (1) made or caused to be made any specific representations concerning Zytiga, which (2) were misleading half-truths due to some statutory, regulatory, or contractual non-compliance. Indeed, Relator fails to identify *any* specific representation made in connection with a claim for payment at all.

2. Relator Fails To Plead A False Statement In Connection With Federal Drug Pricing

Failing to plead specifics in connection with the submission of claims for payment, Relator instead makes allegations in connection with the negotiation of drug prices. Specifically, Relator alleges that the pricing information Defendants submitted to qualify Zytiga for purchase and reimbursement by Government agencies was unfair and unreasonable because the pricing data reflected Zytiga's patent exclusivity. SAC ¶¶ 115, 117. The SAC, however, misrepresents the drug contracting process and rips the phrase "fair and reasonable" from its regulatory moorings.

Relator supplies a meaning for the term "fair and reasonable" that cannot be found in any regulation or contract he cites. *Id.* ¶ 117. Because this is a legal conclusion, the Court need not accept the allegation. *See Druding v. Care Alts., Inc.*, 164 F. Supp. 3d 621, 626 (D.N.J. 2016); *U.S. ex rel. Jersey Strong Pediatrics, LLC v. Wanaque Convalescent Ctr.*, No. 14-6651, 2017 WL 4122598, at *2 (D.N.J. Sept. 18, 2017) As used in the drug price negotiation context, the phrase "fair and reasonable" does not invite a freewheeling inquiry into the subjective fairness of a drug's price or a manufacturer's conduct, but rather refers to a specific, objective relationship between the product's market price and its listed Government price. That relationship defines how much

136 S. Ct. at 2000). That view, however, contradicts the Supreme Court's and Third Circuit's view that the FCA is not intended to police all regulatory non-compliance. *Escobar*, 136 S. Ct. at 2003 (FCA not "all-purpose antifraud statute"); *Wilkins*, 659 F.3d at 307 ("[T]he implied certification theory of liability should not be applied expansively, particularly … from the Government's payment of claims under federally funded health care programs.").

the Government pays for a drug, and the discount formula is unaffected by patent exclusivity.

As the GSA Solicitation that Relator cites explains, SAC ¶ 114, the structured review process conducted by the VA is designed in part "to ensure … the Government is receiving a fair and reasonable price." RJN, Ex. H at CP-11; *see also* 48 C.F.R. § 8.404(d) (prices listed on the FSS have been determined to be "fair and reasonable"). Federal "Contracting Officers determine whether prices are fair and reasonable by comparing the prices/discounts that a company offers the government with the prices/discounts offered to commercial customers." RJN, Ex. H at CP-8. Each quarter, manufacturers provide the VA with the AMP, which is used to calculate the FCP. SAC ¶ 112. They also periodically provide the VA with commercial pricing information, Most Favored Customer information, and Tracking Customer information to allow VA contracting officials to ensure that the prices offered to the Government remain "fair and reasonable" throughout the duration of the contract. *Id.*; RJN, Ex. H at 53. Whether a price is "fair and reasonable" refers only to the comparison between Government and commercial prices.[34] RJN, Ex. H at CP-8. Manufacturers must present accurate information, but the contracting officer decides whether the offered Government price is "fair and reasonable." And while the Government is permitted access to certain records to "verify the pricing, sales and other data related to the supplies or services proposed in order to determine the reasonableness of the price(s)," that "[a]ccess does not extend to [the] offeror's cost or profit information or other data relevant solely to the offeror's determination of the prices to be offered in the catalog or marketplace." *Id.* at 53. In other words, the Government does not consider how a manufacturer arrived at the commercial price of the good—only whether the proposed Government pricing

[34] A manufacturer separately certifies "that it has on file," as required, an FDA-approved new drug application ("NDA") or abbreviated new drug application ("ANDA") "as appropriate for the items offered in response to the solicitation." RJN, Ex. H at 2. The Solicitation makes no further provision for submitting the approval or requiring verification of the NDA or ANDA.

compares favorably to that commercial price.

Relator does not plead that Defendants submitted incorrect commercial pricing data to the VA, misidentified the tracking customer, or made any other incorrect representation to GSA, the VA, or any other federal healthcare agency. Nor does Relator allege that the Zytiga discounts to which the Government agreed were not "fair and reasonable" as compared to that accurate commercial pricing data. Relator claims instead that the pricing information carried an implicit certification that it was not "unlawfully inflated through the exclusion of competitors," SAC ¶ 115, or "the product of an unlawfully extended patent monopoly," *id.* ¶ 117. But Relator cites no authority—nor are Defendants aware of any—holding that a drug's patent prosecution history, or the USPTO's bases for issuing a patent, are incorporated—either expressly or implicitly—into the Government's "fair and reasonable" assessment under the Solicitation. It is simply not part of the equation, and any alleged "implied" certification to that effect is manufactured from whole cloth.

Taken to its logical conclusion, Relator's theory of falsity is shockingly broad. Were the Court to accept Relator's construction of the GSA's "fair and reasonable" requirement, it could swallow *any* regulatory or statutory requirement that might affect product price no matter how attenuated from the claim-submission process. In the patent context alone, this would trigger FCA liability any time a patent is called into question through an infringement action or an IPR, and, in all likelihood, on a much more frequent basis separate and apart from those proceedings. Relator's theory would undermine the Third Circuit's admonition against expansive application of the implied certification theory in the healthcare context, *Wilkins*, 659 F.3d at 307, and unleash the FCA as an "all-purpose antifraud statute" despite the Supreme Court's explicit instructions to the contrary, *Escobar*, 136 S. Ct. at 2003. The Court should dismiss those claims grounded in a false-certification theory of FCA liability.

3. Relator Fails To Plead A Promissory Fraud Theory Of Liability

The SAC separately asserts that the alleged misconduct before the USPTO amounted to an "upstream fraud" that "taints claims for payment later submitted to the government." SAC ¶ 106. This promissory fraud-style theory is a "narrow, third category of false claims obtained by 'fraud-in-the-inducement,'" wherein FCA liability may attach to payments made pursuant to a fraudulently induced *contract*. *Plavix II*, 332 F. Supp. 3d at 939 (quoting *United States v. Veneziale*, 268 F.2d 504, 505 (3d Cir. 1959)). But Relator does not allege the purported fraud resulted in a contract, and this Court has declined to extend this theory to non-contract situations.

In codifying this theory, Congress limited it to "to claims 'under a contract, loan guarantee, or other agreement.'" *See Plavix II*, 332 F. Supp. 3d at 952 (quoting S. Rep. No. 99-345, at 9 (1986), *reprinted in* 1986 U.S.C.C.A.N. at 5266, 5274). Nor has the Third Circuit applied it outside the context of a contract. *Id*. And, in *Plavix II*, this Court expressly rejected an expansion of the promissory fraud theory to allegations of fraud, like Relator's, that arise "in the context of non-contract interactions with government regulatory bodies." *Id*. There is a "direct causal connection" between "contracts induced by fraud and claims submitted under those contracts" that prevents this theory from converting the FCA into an "all purpose antifraud statute." *Id.* at 953. As this case starkly illustrates, that same causal connection is absent from non-contract situations because the purported fraud does not "give rise to the later claims submitted for payment to the government." *Id.* at 952–53. In other words, while Relator claims Defendants' purported fraud led to the issuance of the '438 Patent—thereby "taint[ing]" all subsequent payments for Zytiga, SAC ¶ 44; *id.* ¶ 107—nothing about that Patent induced physicians to prescribe, or the Government to reimburse claims for, Zytiga.

To "embrac[e] Relator's theory would be a step toward bringing all misrepresentations to government bodies within the purview of the FCA." *Plavix II*, 332 F. Supp. 3d at 953; *cf. U.S. ex*

rel. Promega Corp. v. Hoffman-La Roche Inc., No. 03-1447-A (E.D. Va. Sept. 24, 2004) ("misrepresentations to the USPTO" years prior were "disconnect[ed]" from "invoices submitted to the government" and failed to state an FCA claim) (attached hereto as Appendix A). But the Third Circuit has been firm that the FCA "is not 'a blunt instrument to enforce compliance with all … regulations.'" *Wilkins*, 659 F.3d at 307.

Because the alleged fraud resulted in a patent and not a contract, Relator's promissory fraud theory must also be dismissed.

B. Relator Fails To Plead Materiality

The SAC also founders on *Escobar*'s "demanding" materiality standard. *See Escobar*, 136 S. Ct. at 2003–04; *see also Petratos*, 855 F.3d at 489. Relator has not pled "facts to support allegations of materiality" "with plausibility and particularity." *See Escobar*, 136 S. Ct. at 2004 n.6. In the context of implied false certification, "a plaintiff must show that if the Government had been aware of the defendant's violations of the [relevant] laws and regulations that are the bases of a plaintiff's FCA claims, it would not have paid the defendant's claims." *Plavix II*, 332 F. Supp. 3d at 939 (quoting *Wilkins*, 659 F.3d at 307). And "statutory, regulatory, and contractual requirements are not automatically material, even if they are labeled conditions of payment." *Escobar*, 136 S. Ct. at 2001.

Relator's allegations here are both conclusory and implausible. His allegation that "price … is *per se* material to the government's payment decision," SAC ¶ 123, is insufficient as a matter of law. *See Escobar*, 136 S. Ct. at 2003 ("decision to expressly identify a provision as a condition of payment is relevant, but not automatically dispositive"). It also falls far short of the generally required Rule 8 pleading standard, *Iqbal*, 556 U.S. at 678, let alone the more rigorous requirements of Rule 9(b). And Relator has offered no authority that the "fair and reasonable requirement"—

assuming it could even be read as Relator suggests—is an express condition of payment. *Escobar* further requires Relator to show Defendants *knew* the "fair and reasonable" requirement (at least as Relator construes it) was material to the payment of a claim. *Escobar*, 136 S. Ct. at 1996 (liability may lie only when "the defendant knowingly violated a requirement that the defendant knows is material"). Relator has made no such allegations.

Nor does the SAC contain any other allegation suggesting patent-related misconduct would influence other agencies' decisions to pay. For instance, Relator does not allege that any agency stopped reimbursing Zytiga following his allegations. *See Escobar*, 136 S. Ct. at 2003–04. To the contrary, the Government subsequently investigated Relator's claims, elected *not* to intervene, and Zytiga has remained on the FSS from that day to this,[35] suggesting that the Government has identified no reason to stop paying for it.[36] Indeed, Relator concedes that the Government "paid and *continues* to pay" claims for Zytiga, SAC ¶ 144 (emphasis added), which strongly indicates that the purported violations are not material to the Government's decision to pay. *See Petratos*, 855 F.3d at 490 ("Simply put, a misrepresentation is not 'material to the Government's payment decision,' when the relator concedes that the Government would have paid the claims with full knowledge of the alleged noncompliance."); *cf. D'Agostino v. ev3, Inc.*, 845 F.3d 1, 7 (1st Cir. 2016) ("The fact that CMS has not denied reimbursement for [defendant's product] in the wake of [the relator's] allegations casts serious doubt on the materiality of the fraudulent representations that [the relator] alleges.").

[35] *See* RJN, Ex. GG (FSS for Zytiga 250MG Tab); RJN, Ex. HH (FSS for Zytiga 500MG Tab).

[36] The Solicitation grants the GSA the power to review a vendor's books and records to verify that the pricing offered for a good is fair and reasonable. RJN, Ex. H at 22, 53. The GSA "may" also terminate a contract for violation of a term or condition. *Id.* at 6. But a showing that "the Government would have the option to refuse payment of Defendants' claims … is insufficient to show materiality" under *Escobar*. *Dr. Reddy's Labs.*, 2017 WL 1133956 at *16.

Other facts indicative of materiality may include "evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement." *U.S. ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89, 94 (3d Cir. 2018) (quoting *Escobar*, 136 S. Ct. at 2003). Relator lists a handful of enforcement actions undertaken by the Government in an effort to show that "[t]he government has repeatedly confirmed, by word and deed, that drug price manipulation is material to its payment decision." SAC ¶ 126.[37] But Relator does not and cannot allege that any of these situations involved the Government *refusing to pay claims for products because of an alleged fraud in connection with an underlying patent*. None of Relator's examples demonstrates "the effect on the likely or actual behavior of the [Government] of the alleged misrepresentation." *Escobar*, 136 S. Ct. at 2002–03. That is what matters for FCA liability.

III. RELATOR FAILS TO PLEAD INEQUITABLE CONDUCT BEFORE THE USPTO

Even if one of the above theories were viable (which they are not), each depends on Relator's underlying contention that Defendants engaged in inequitable conduct before the USPTO—that is, made misrepresentations and omissions in violation of the duty of candor and procured the '438 Patent through fraud. *See Avid Identification Sys., Inc. v. Crystal Import Corp.*, 603 F.3d 967, 974 n.1 (Fed. Cir. 2010); *Pac. Biosciences of Cal., Inc. v. Oxford Nanopore Techs., Inc.*, No. 17-275-LPS, 2019 WL 668843, at *3 (D. Del. Feb. 19, 2019). Because Relator's FCA claim is premised on an alleged breach of this duty, he must plead a violation of that duty—*i.e.*, a claim for inequitable conduct. To require otherwise would be to allow Relator to end run around

[37] *See* SAC ¶ 127 (case citation to government-instituted civil litigation against pharmaceutical company for sham litigation that does not reference any decision by government to stop paying for the allegedly artificially priced products); *id.* ¶ 128 (press release highlighting guilty plea of South Korean companies engaged in bid-rigging to sell military fuel); *id.* ¶ 129 (civil suit filed against 20 generic pharmaceutical companies for conspiracy to price-fix and market-share); *id.* ¶ 130 (allegations of price-fixing, bid-rigging, and market allocation that led to deferred prosecution and civil settlement for claims under the FCA and Anti-kickback Statute).

patent law, using the FCA to create liability for invalidated patents where none would otherwise exist. As described below, Relator pleads no facts to support that claim.

To begin with, the duty of candor attaches not to companies, but to *individuals* appearing before the USPTO.[38] *See* 37 C.F.R. § 1.56; *Avid Identification Sys., Inc.*, 603 F.3d at 974 n.1; *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1329 (Fed. Cir. 2009) (citing Manual of Patent Examining Procedures § 2001.01). Accordingly, courts routinely reject allegations that fail to identify individual wrongdoers. *See, e.g.*, *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1329 (Fed. Cir. 2009); *Senju Pharm. Co. v. Apotex, Inc.*, 921 F. Supp. 2d 297, 307 (D. Del. 2013) (a "broadly cast net around the inventors and those acting on their behalf does not allow the court to reasonably infer that a specific individual both knew of the invalidating information and had a specific intent to deceive the PTO").

As to the specific individual(s) owing a duty of candor, Relator must demonstrate that they "acted with the specific intent to deceive." *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1288–90 (Fed. Cir. 2011) (en banc).[39] Specific intent, in turn, requires facts sufficient to show that "the applicant knew of the [information being withheld], knew that it was material, and made a deliberate decision to withhold it." *Id.* at 1290. But even then, Relator must further demonstrate that the purported malfeasance was the "but-for" cause for the patent to issue, *id.* at

[38] Individuals owing a duty of candor include: the inventor; the preparer or prosecutor of the application; and persons who are substantively involved in the preparation or prosecution of the application and are associated with the inventor or applicant, or anyone who is assigned the application. 37 C.F.R. § 1.56(c)(1)–(3).

[39] While "no proof of specific intent to defraud" is necessary to show that a false claim was knowingly submitted under the FCA, 31 U.S.C. § 3729(b)(1)(B), that does not relieve a relator from pleading and then proving whatever threshold elements are required to substantiate a claimed predicate statutory or regulatory violation. Here, because Relator's FCA claim is based on the predicate act of inequitable conduct, Relator must plead and prove the specific intent required to substantiate such a claim, before any claim for payment could be deemed false (under Relator's misguided legal theory).

1291, which requires the accuser to provide independent proof of but-for materiality, *see id.* at 1292–93. And, because inequitable conduct sounds in fraud, such claims must be pleaded with particularity, again reporting the "who, what, when, where, and how" of the claimed fraudulent conduct. *Exergen*, 575 F.3d at 1327; *see also Eagle View Techs., Inc. v. Xactware Sols., Inc.*, 325 F.R.D. 90, 93–94 (D.N.J. 2018). Even allegations of specific intent must be "reasonable and drawn from a pleading's allegations of underlying fact." *Exergen Corp.*, 575 F.3d at 1329 n.5. Relator falls far short of these requirements.

Relator names five corporate defendants and broadly attributes various misrepresentations and omissions to them generally. SAC ¶¶ 19–26, 59–91. While the SAC now identifies individual inventors and applicants of the '438 Patent as well as the attorney who prosecuted the '438 Patent and signed the June 4 submission, *id.* ¶¶ 70–71, 91, it does not allege the required elements of an inequitable conduct claim as to those named individuals. *See Delano Farms Co. v. Cal. Table Grape Comm'n*, 655 F.3d 1337, 1350 (Fed. Cir. 2011) (complaints asserting inequitable conduct must "recite[] facts from which the court may reasonably infer that *a specific individual* both knew of invalidating information that was withheld from the PTO and withheld that information with a specific intent to deceive the PTO" (emphasis added)); *Breville Pty Ltd. v. Storebound LLC*, No. 12-cv-01783-JST, 2013 WL 1758742, at *4–6 (N.D. Cal. Apr. 24, 2013). And while Relator attempts to link the broadly attributed conduct to specific individuals through an agency relationship, that relationship does not confer individual knowledge of the facts and the materiality of the misrepresentation or a specific intent to deceive the USPTO by deliberately withholding the information. *See Breville Pty. Ltd.*, 2013 WL 1758742, at *6.[40]

[40] For example, certain allegations or omissions are predicated on the individual owing the duty being "skilled in the relevant arts" without pleading any facts to suggest that the individual was, in fact, so skilled. *E.g.*, SAC ¶ 84(f).

The SAC suffers from other defects, as well. Certain allegations are not actionable as affirmative statements, *see, e.g.*, SAC ¶ 84(a)–(d) (withholding of FDA approval date that had not yet occurred); *id.* ¶ 87(a) (opinion statement that Zytiga was the most successful oral oncology launch of all time); *id.* ¶ 87(b), (f) (speculating as to causes of success), while others plead no facts linking the individual omission's or misrepresentation's materiality to the patent's issuance, *Exergen*, 575 F.3d at 1329–30; *see, e.g.*, SAC ¶ 84(e) (claiming improper market-share metric without evaluating effect on examiner); *id.* ¶ 121 ("But for Defendants' misrepresentations … the Patent Office would never have issued the '438 Patent.").[41] In fact, undermining any suggestion of materiality of the various alleged omissions, Relator pleads that "the single most reasonable explanation for the Patent Office's approval of the '438 Patent was Defendants' fraudulent and misleading statements concerning Zytiga's growth in the chemo-naïve market." *id.* ¶ 86.

Finally, certain of Relator's allegations are flatly disproven by the very documents he cites. *See In re Intelligroup Sec. Litig.*, 527 F. Supp. 2d 262, 273–74 (D.N.J. 2007) (court may take judicial notice of public documents). As discussed above, *supra* at 17–20, many of the purported omissions or misrepresentations were disclosed to the patent examiner during patent prosecution. For example, the '213 Patent is specifically disclosed in the specification of the '438 Patent, and the '340 Application examiner expressly acknowledged considering the '213 Patent during prosecution of the '438 Patent's parent application, *compare* SAC ¶ 87(e), *with* RJN, Ex. I at 7, 10; RJN, Ex. J at 379 of 384 (PDF page) (excerpt from '340 patent application), undermining any claim of intent to deceive, *see Pac. Biosciences*, 2019 WL 668843, at *3, or materiality, *see Therasense*, 649 F.3d at 1291. That disclosure is fatal to Relator's fraud claim. *See, e.g.*, *Scripps*

[41] Still other allegations are immaterial on their face, such as allegations concerning the short-term efficacy of *all* mCRPC drugs; market advantages from being first to launch; cost; modes of administration; and the overall poor prognosis of mCRPC patients. *See generally* SAC ¶ 87.

Clinic & Research Found. v. Genentech, Inc., 927 F.2d 1565, 1582 (Fed. Cir. 1991), *overruled on other grounds by Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282 (Fed. Cir. 2009).

At most, Relator contends that Defendants should have presented the commercial success arguments differently; but that is not a basis for fraud on the USPTO. While "the law prohibits genuine misrepresentations of material *fact*," "a prosecuting attorney is free to present argument in favor of patentability without fear of committing inequitable conduct." *Rothman v. Target Corp.*, 556 F.3d 1310, 1328–29 (Fed. Cir. 2009) (emphasis added). It is then up to the examiner's "discretion to reject or accept an applicant's arguments based on the examiner's own conclusions regarding the prosecution record." *Id.* at 1329; *see also Cherdak v. Vock*, No. 11-cv-1311, 2012 WL 1427847, at *1 (E.D. Va. Apr. 23, 2012) (submission that "consist[ed] of attorney argument and an interpretation of what the prior art discloses" could not "constitute affirmative misrepresentations of material fact"). Because Relator has not properly pled fraud on the USPTO years ago, his allegations cannot support a claim for FCA liability today.

IV. RELATOR'S CLAIMS AGAINST BTG SHOULD BE DISMISSED FOR ADDITIONAL AND INDEPENDENT REASONS

Relator's claims against Defendant BTG should be dismissed for all of the reasons given so far. But the claims against BTG—added as a defendant in the SAC for the first time—also fail for two additional reasons.

First, Relator's own allegations expressly acknowledge that BTG had no role in the prosecution of the '438 Patent—the proceeding in which Relator alleges the root misrepresentations were made—nor in the submission of pricing information to the Government—the process in which Relator alleges promises of "fair and reasonable" prices were made. Thus, Relator does not and cannot allege that BTG either caused the submission of false claims or did so with the requisite scienter.

The gravamen of Relator's claims is that Defendants perpetrated a fraud on the USPTO by submitting an application for the '438 Patent that—he asserts—included material misstatements and omissions. But Relator makes no allegations that BTG played any role in securing the '438 Patent; nor could he because, as the SAC acknowledges, the correction of inventorship that recognized BTG's co-ownership occurred "[s]ubsequent to the issuance of the '438 patent," SAC ¶ 91, indeed many years later.[42] Not only does Relator fail to allege that BTG made a misleading statement to the USPTO, he also does not allege that BTG played any role in negotiating the federal list price for Zytiga. Without such allegations, Relator does not and cannot allege that BTG caused the submission of false claims, let alone did so knowingly.

Second, and consistent with these fatal shortcomings, Relator's allegations against BTG are not pled with particularity, as required by Federal Rule of Civil Procedure 9(b). That rule requires plaintiffs alleging fraud, including FCA relators, to "state with particularity the circumstances constituting fraud or mistake," Fed. R. Civ. P. 9(b); *see Foglia*, 754 F.3d at 155, including "the who, what, when, where and how of the events at issue." *Moore*, 812 F.3d at 307 (quoting *In re Rockefeller Ctr. Props., Inc. Sec. Litig.*, 311 F.3d 198, 217 (3d Cir. 2002)). With respect to BTG, Relator's claims wholly fail to satisfy this standard.

The SAC mentions BTG in only three of its 496 paragraphs. *See* SAC ¶ 23 (BTG is a U.K. corporation); *id.* ¶ 25 (BTG "asserts co-ownership of the '438 patent"); *id.* ¶ 91 (BTG asserts co-ownership in its role as "the owner of" the inventions of Dr. Johann S. de Bono). These allegations against BTG fail Rule 8's requirements, let alone Rule 9(b)'s.

[42] Paragraph 91 states in full:

> Subsequent to the issuance of the '438 patent, there was a proceeding to correct inventorship in which Dr. Johann S. de Bono was added as an inventor to the '438 patent. BTG is the owner of Dr. de Bono's inventions and thus asserts co-ownership of the '438 patent along with Janssen.

That Relator makes allegations against "Defendants" collectively, without identifying which Defendant he avers did what, does not satisfy his pleading burden. As multiple courts of appeals have held, "Rule 9(b) does not allow a complaint to merely lump multiple defendants together but requires plaintiffs to differentiate their allegations when suing more than one defendant and inform each defendant separately of the allegations surrounding his alleged participation in the fraud." *Swartz v. KPMG LLP*, 476 F.3d 756, 764–65 (9th Cir. 2007) (per curiam) (alterations omitted); *see Cornielsen v. Infinium Capital Mgmt., LLC*, 916 F.3d 589, 599 (7th Cir. 2019) ("[A] complaint that attributes misrepresentations to all defendants, lumped together for pleading purposes, generally is insufficient."); *Mills v. Polar Molecular Corp.*, 12 F.3d 1170, 1175 (2d Cir. 1993) ("Rule 9(b) is not satisfied where the complaint vaguely attributes the alleged fraudulent statements to 'defendants.'"). A relator thus cannot satisfy Rule 9(b) in gross; he must, "at a minimum[,] identify the role of each defendant in the alleged fraudulent scheme." *U.S. ex rel. Lee v. Corinthian Colls.*, 655 F.3d 984, 998 (9th Cir. 2011). That rule makes good sense. Rule 9(b) is designed to give defendants "notice of the claims against them, [to] provide[] an increased measure of protection for their reputations, and [to] reduce[] the number of frivolous suits brought solely to extract settlements." *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1418 (3d Cir. 1997). Vague and conclusory allegations that fail to differentiate meaningfully between the actions allegedly taken by one defendant and those taken by another defeat those purposes. Because, as to BTG, the SAC proceeds on a theory that "vaguely attributes the alleged fraudulent statements "to 'defendants,'" *Mills*, 12 F.3d at 1175, it fails to meet the heightened pleading requirement of Rule 9(b) and should be dismissed.

CONCLUSION

All claims against all Defendants should be dismissed for the reasons stated in Parts I through III above. But in any event, the claims against BTG should be dismissed for the additional and independent reasons set forth in this Part IV. And, as this represents Relator's third bite at the apple, the Court should dismiss the SAC with prejudice.[43]

Dated: September 13, 2019

Respectfully submitted,

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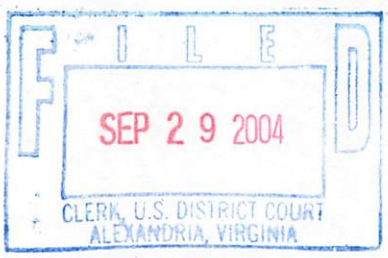
[43] For all of the same reasons, Relator has failed to plead a cause of action under the Plaintiff States' statutes, and Relator has further failed to plead any facts in support of Count XXI under the New Mexico Fraud Against Taxpayers Act, SAC ¶¶ 373–376.

APPENDIX A

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA

Alexandria Division



UNITED STATES OF AMERICA, ex rel. PROMEGA CORPORATION, et al.,	
Plaintiffs,	
v.	Civil Action No. 03-1447-A
HOFFMAN-LA ROCHE INC., et al.,	
Defendants.	

ORDER

This matter comes before the Court on Motions to Dismiss the Amended Complaint filed by Defendants Hoffman-LaRoche Inc. and Roche Molecular Systems, Inc. as well as by Defendants PE Corporation, PE Biosystems Group, the Perkin-Elmer Corporation, and PE Applied Biosystems.

For the reasons stated in the accompanying memorandum opinion, it is hereby

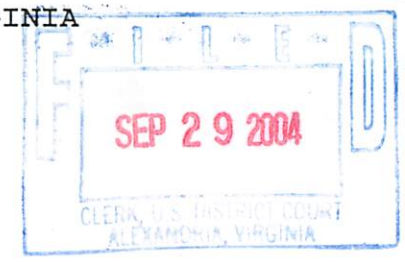
ORDERED that all Defendants' Motions to Dismiss are GRANTED and the case is DISMISSED with PREJUDICE.

Claude M. Hilton
CHIEF UNITED STATES DISTRICT JUDGE

Alexandria, Virginia
September 29, 2004

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA

Alexandria Division



UNITED STATES OF AMERICA, ex rel. PROMEGA CORPORATION, et al.,	
Plaintiffs,	
v.	Civil Action No. 03-1447-A
HOFFMAN-LA ROCHE INC., et al.,	
Defendants.	

MEMORANDUM OPINION

This matter comes before the Court on Motions to Dismiss the Amended Complaint filed by Defendants Hoffman-LaRoche Inc. and Roche Molecular Systems, Inc. as well as by Defendants PE Corporation, PE Biosystems Group, the Perkin-Elmer Corporation, and PE Applied Biosystems. Defendants assert that Plaintiffs' claims should be dismissed under Federal Rule of Civil Procedure 12(b)(1) for lack of subject matter jurisdiction and under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim upon which relief may be granted.

Plaintiffs filed the instant case on April 23, 2000 alleging violations of the False Claims Act, pursuant to 31 U.S.C. § 3729 (2003). This Court dismissed Plaintiffs' Complaint without

prejudice pursuant to Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim with sufficient particularity as required by Federal Rule of Civil Procedure 9(b). On July 13, 2004, Plaintiffs filed an Amended Complaint alleging that Defendants violated the False Claims Act on nine counts.

In Counts I through III of the Amended Complaint, Plaintiffs allege that "every claim, invoice, demand, solicitation, representation, relationship, contract or transaction" sent to the United States Government or government-funded entities for payment by the Defendants was a false or fraudulent claim in violation of section 3729(a)(1) of the False Claims Act because Defendants based all of these claims on "fraudulently obtained" patents. Am. Compl. ¶¶ 260-283. In Counts IV through VI, Plaintiffs allege that Defendants used false records or statements to get the United States Government or government-funded entities to pay false or fraudulent claims, in violation of section 3729(a)(2) of the False Claims Act.

Count VII alleges a conspiracy between the Defendants to fraudulently obtain patents for Taq and then submit false claims for payment to the United States Government based on those patents, in violation of section 3729(a)(3) of the False Claims Act. In Count VIII, Plaintiffs allege that Defendants used false

statements or records to conceal or avoid repayment of monies to the United States Government in violation of section 3729(a)(7) of the False Claims Act. Finally, in Count IX, Plaintiffs allege that Defendants wrongfully retained monies properly owed to the United States, in violation of section 3729(a)(4) of the False Claims Act. Plaintiffs seek $128 million dollars in damages and ask the Court to treble those damages.

When ruling on a motion to dismiss, this Court must "assume the truth of all facts alleged in the complaint and the existence of any fact that can be proved, consistent with the complaint's allegations." Eastern Shore Markets, Inc. v. J.D. Assocs. Ltd. P'ship, 213 F.3d 175, 180 (4th Cir. 2000). While the Court must consider the facts in the light most favorable to the plaintiff, unreasonable conclusions without factual support, unwarranted inferences, and arguments are insufficient to state a claim upon which relief can be granted. Id.

Defendants move to dismiss under 12(b)(6) for failure to state a claim with the sufficient particularity required under Rule 9(b) of the Federal Rules of Civil Procedure. Fed. R. Civ. P. 9(b) (2004). Claims brought under the False Claims Act are charges of fraud and are subject to Rule 9(b) under which plaintiffs must plead their complaint with particularity.

Harrison v. Westinghouse Savannah River Co., 176 F.3d 776, 783-84 (4th Cir. 1999); See Fed. R. Civ. P. 9(b) (2004). A Complaint's "lack of compliance with 9(b)'s pleading requirements is treated as a failure to state a claim under 12(b)(6)." Harrison, 176 F.3d at 783 n. 5. Particularity in pleading refers to "the time, place, and contents of the false representations, as well as the identity of the person making the misrepresentation and what he obtained thereby." Id. at 784 (citing 5 Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure: Civil § 1297, at 590 (2d ed. 1990)). In other words, the Complaint must state the "who, what, when, where, and how" of the fraud to plead it with sufficient particularity. United States ex rel. Detrick v. Daniel F. Young, Inc., 909 F. Supp. 1010, 1022 (E.D. Va. 1995).

Plaintiffs' Amended Complaint expands their three original counts into nine counts and adds over seventy pages of details to their original Complaint. Despite all of these additions, Plaintiffs have failed to plead the essential elements and details with sufficient particularity to withstand 9(b) scrutiny. Just as in the original Complaint, Plaintiffs continue to outline vague, broad schemes.

In Counts I through VI, Plaintiffs fail to describe what was obtained through the alleged fraud. Instead, the Amended

Complaint repeats the same vague allegations of higher prices, see, e.g., Am. Compl. ¶ 168, and generalized platitudes regarding the "reduced overall competition in the Taq market," see, e.g., Am. Compl. ¶¶ 180-82.

Furthermore, Counts I through VI fail to specify when and where the false claims were made. The invoices themselves were not fraudulent, because they contained the exact terms agreed to by the Government. Instead, Plaintiffs allege that Defendants' predecessors made misrepresentations to the USPTO in order to obtain certain patents, and that years later Defendants used those patents to obtain contracts with the Government. Under Plaintiffs' theory, every invoice submitted for payment under these contracts violated the False Claims Act because of the misrepresentations to the USPTO from years ago. This theory is fatally flawed because there is a disconnect between the alleged misrepresentations to the USPTO and the invoices submitted to the Government, and Plaintiffs fail to draw a meaningful connection between the two.

Plaintiffs attempt to resolve this disconnect by claiming that the misrepresentations somehow induced the Government to enter into contracts with the Defendants. Plaintiffs have failed, however, to allege any facts that support such a theory.

Paragraph 136, for example, alleges that "[o]n information and belief, employees, independent contractors, agents or representatives of Defendants . . . discussed the obligation to pay certain prices for Taq and related products/processes." This paragraph, however, fails to explain who these agents were, what they said, to whom, in what context and capacity, about what products; therefore, it is too vague to satisfy the 9(b) requirement.

Count VII alleges a conspiracy dating all the way back to a meeting on December 18, 1988. The Amended Complaint does not identify the role that each Defendant played in the conspiracy and more importantly, it fails to identify Defendants' culpable conduct. The Amended Complaint refers merely to "conspiracy meetings" in which the Defendants discussed "marketing plans," "pricing and royalty rates" and "Taq sales." Am. Compl. ¶ 101. It appears to the Court that Plaintiffs are merely alleging facially legal conduct and labeling it a "conspiracy." This sort of fishing expedition is exemplary of the conduct that Federal Rule of Civil Procedure 9(b) seeks to prevent.

Finally, Plaintiffs have failed to sufficiently plead the statutory elements required under 31 U.S.C. §§ 3729(a)(4) & (7) and accordingly Counts VIII and IX should be dismissed. Under §

3729(a)(7), Plaintiffs must show that Defendants "knowingly [made] . . . a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government." 31 U.S.C. § 3729(a)(7). While Plaintiffs allege that this "obligation" accrued as a result of Defendants' failure to observe certain unidentified "fiduciary and contractual" duties owed to the Government, neither the duties nor any wrongfully obtained monies are identified. Nor do Plaintiffs identify what false statement was made by whom at the time a legal duty to pay the Government arose. Accordingly, Count VIII should be dismissed.

Similarly, § 3729(a)(4) imposes liability if a Defendant "has possession, custody, or control of property or money used . . . by the Government and, intending to defraud the Government or willfully to conceal the property, delivers . . . less property than the amount for which the person receives a certificate or receipt." 31 U.S.C. § 3729(a)(4). The Amended Complaint alleges that Defendants concealed an overpayment by the Government, but fails to allege the delivery of property to the United States in return for a receipt. Since Plaintiffs have failed to plead all of the essential elements of § 3729(a)(4), Count IX should be dismissed.

Even if the court found that Plaintiffs did state a claim for relief, the Amended Complaint should be dismissed pursuant to Federal Rule of Civil Procedure 12(b)(1) because the court lacks subject matter jurisdiction to hear the case. Under the False Claims Act, there is a two step inquiry to determine whether a court has subject matter jurisdiction. First, the court must determine whether the action is "based upon the public disclosure of allegations or transactions." If the action is based upon public disclosure, the court must then determine whether the plaintiff qualifies as an "original source." 31 U.S.C. § 3730(e)(4)(A) (2003).

In the first inquiry, the term "based upon" means derived from, such that the action is based upon public disclosure only where the plaintiff has actually derived from that disclosure knowledge of facts underlying the action. United States ex rel Siller v. Becton Dickinson & Co. by & Through Its Microbiology Sys. Dev., 21 F.3d 1339, 1348 (4th Cir. 1994). The present action is, in fact, derived from public information. Plaintiffs base their complaint on information from administrative and civil proceedings, litigation before the United States District Court for the Northern District of California, discovery in this very case, the news media, marketplace activities and public

statements. The publicly filed patents themselves provided the basis for Plaintiff's information leading to claims of fraudulent patent applications. Dimond Dep. ¶¶ 17:11-17:20, 20:23-21:2; 2d Dimond Aff. ¶¶ 13-14. All of Plaintiffs' "independent study and analysis" was derived from those public filings. Furthermore, Plaintiffs rely heavily on information obtained from Hoffmann-La Roche, Inc. et al. v. Promega Corp., 1999 U.S. Dist. LEXIS 19059 (N.D. Cal. 1999). Am. Compl. ¶ 46. In fact, practically all of Plaintiffs' allegations regarding the alleged fraudulent claims and the alleged conspiracy comes directly from public information. Am. Compl. ¶ 62.

Once it is established that the Plaintiffs based their claim upon public information, the second inquiry to determine subject matter jurisdiction asks whether the Plaintiffs qualify as an "original source" of the public information. A party is an original source if they have "direct and independent knowledge of the information on which the allegations are based and [have] voluntarily provided the information to the Government before filing an action under this section." 31 U.S.C. § 3730(e)(4)(B) (2002). According to the Fourth Circuit, a relator has direct knowledge "if he acquired it through his own efforts, without an intervening agency." Grayson v. Advanced Management Technology,

Inc., 221 F.3d 580, 583 (4th Cir. 2000). A relator has independent knowledge "if the knowledge is not dependent on a public disclosure." Id. In the present case, Plaintiffs depend heavily on the litigation in the California District Court and on other public disclosures. Plaintiffs' knowledge is neither direct nor independent. The Plaintiffs are not an original source as defined under the False Claims Act.

An appropriate Order shall issue.

Claude M. Hilton
CHIEF UNITED STATES DISTRICT JUDGE

Alexandria, Virginia
September 29, 2004